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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/943,776	10/03/1997	MARIAPIA A. DEGLI-ESPOSTI	2849-A	9687
22932	7590	02/10/2005	EXAMINER	
IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119			SPECTOR, LORRAINE	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/943,776

**Applicant(s)**

DEGLI-ESPOSTI ET AL.

**Examiner**

Lorraine Spector, Ph.D.

**Art Unit**

1647

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,7,10,11,13,14,16 and 20-43 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33,35-38,41 and 42 is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,10,11,13,14,16,22-32,34,39 and 43 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☒ Claim(s) 1,3,6,7,10,11,13,14,16 and 20-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 3, 6, 7, 10, 11, 13-14, 16, and 20-43 are pending.

Claims 1, 3, 6, 7, 10, 11, 13-14, 16 and 33-43 are under consideration.

The previous rejection of Claims 3, 7, 11, 14 and 26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's arguments.

### ***Double Patenting***

Claim 40 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 33. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is indefinite for reciting the plural "fragments thereof", followed by the singular "the fragment". The plural form is further indefinite because it is not clear how many fragments are to be present. Amendment of "fragments" to read --a fragment-- would be remedial.

The remaining claims are rejected for depending from an indefinite claim.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 7, 11, 14, 22-28, 31-32, 39 and 43 are/remain rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al., U.S. Patent Number 6,153,402, for reasons of record in the previous Office Action, paper number 13. With respect to fusion proteins, see column 16 and claims 55-56. With respect to variants, see column 12, wherein it is stated that the invention includes nucleic acids 90% identical which encode functional proteins, and columns 17-20, which disclose polypeptide variants. With respect to newly filed claim 39, the word “having” is open terminology, such that the claim reads on a process for preparing a protein comprising a fragment of residues 1-411 of SEQ ID NO:6. As the protein of Yu comprises multiple fragments of SEQ ID NO: 6, the claim is anticipated by Yu. Similarly, claim 43 is interpreted as encompassing ‘an isolated polypeptide comprising an amino acid sequence (any portion of the whole) that is at least 70% identical to SEQ ID NO: 6 wherein the polypeptide is capable of inducing apoptosis. As Yu’s protein comprises many fragments that are at least 70% identical to SEQ ID NO: 6, and as Yu’s protein induces apoptosis, the claim is anticipated by Yu.

Applicants traverse that the protein of Yu is not 98% identical to that of SEQ ID NO: 2. This argument has been fully considered but is not deemed persuasive because claim 3 states “at least about 98% identical to amino acids 1 through 417 of SEQ ID NO: 2”. The sequence of Yu et al. has 409 matches over the 417 residues of SEQ ID NO: 2, which is 98%. The limitation that the GAP program is used for the calculation is given minimal weight, as no parameters are specified.

Claims 1, 3, 6, 7, 10, 11, 13-14, 16 and 22-32, 39 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,462,176 and US Patent Application Publication US2002/0192729 A1 (Ashkenazi-1 and -2), both cited by applicants.

Ashkenazi-1 and -2 both disclose Apo-3 protein, which is 100% identical to SEQ ID NO: 2 of the instant application, see SEQ ID NO: 10 of the '176 patent. The '176 patent also discloses and claims fragments and Ig fusions. See also claims 19-39 of Ashkenazi-2. Both documents merit priority to 9/23/1996, one and one-half weeks prior to the earliest priority date. For interpretation of claims 39 and 43, see the rejection over Yu, above.

Applicants are reminded that in order to provoke an interference, applicants must file a statement in accordance with 37 C.F.R. § 1.608(a), see MPEP 2308.01.

### ***Conclusion***

Claims 33, 35-58 and 41-42 are allowable.

Claim 40 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lorraine Spector, Ph.D.  
Primary Examiner

2/8/05